Medtronic

CARDIOBLATE® 68000

SURGICAL ABLATION SYSTEM

Technical Manual

CE 0123

Explanation of symbols

	Conformité Européenne (European Conformity). This Symbol Means That The Device Fully Complies With The MDD Directive (93/42/EEC).
	Attention, See Instructions for Use
	Dangerous Voltage
	Reorder Number
	Serial Number
	Manufacturer
	Temperature Limitation
	Nonsterile
	Fragile, Handle with Care
	Keep Dry
	Content
	Atmospheric Pressure Limitation
	Humidity Limitation
	Date Of Manufacture
	Type CF Applied Part
	Neutral Electrode Isolated from Earth High Frequency
	Dispersive Electrode Pad
	Electrogram

	Monopolar
	Bipolar
	Danger: Explosion Risk if Used with Flammable Anesthetics
	With Respect To Electric Shock Fire And Mechanical Hazards Only In Accordance With Ul60601-1/CAN/CSA C22.2 No. 601.1
	ETL Listing (US/CAN) This device meets the requirement of UL60601, CAN/CSA C22.2 No. 601-1M90 and IEC60601-2-2
	Non-ionizing Radiation
	Fuse Marking: Replace Fuses as Marked
	Do not dispose of this product in the unsorted municipal waste stream.
	Bipolar Device
	Monopolar Device
	Overall RF Energy Delivery Time
	Transmural
	Remote Control Foot Switch
	Graph Mode
	Volume Level
	Impedance
	Wattage
Ω	Ohms, Unit of Impedance Measurement
RF	RF Energy Delivery Button
	Active Ablation Time

	Universal Serial Bus (USB) Port Connector
?	Error Message Explanation
W	Watts, Unit of Energy Measurement
	Maximum Limit
	Minimum Limit
	OFF (AC Power)
	ON (AC Power)
	Warning or Error Message
! USA	For US Audiences Only

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How to Use This Manual

This guide presents information for users of the Model 68000 Cardioblate® Generator. It contains information about the following:

- **Overview**

  This chapter is a brief overview of the Cardioblate® Generator and the accessories that compose the Cardioblate® Surgical Ablation System.

- **Generator Description**

  This chapter identifies and describes the generator case, controls, connectors, touch-screen information fields, and touch-screen interactive fields.

- **Generator Operation**

  This chapter provides instructions for preparing the patient, setting up the generator system, and treating the patient.

- **Safety Shutdown and Troubleshooting**

  This chapter provides information on safety shutdown conditions and messages and trouble-shooting.

- **Device Maintenance and Service**

  This chapter identifies how to replace the fuse and clean the generator and provides information on technical and safety inspections.

- **Warranty**

  This chapter describes the device and accessories warranties.

Changing the Language Option

This information is also provided in Chapter 3.

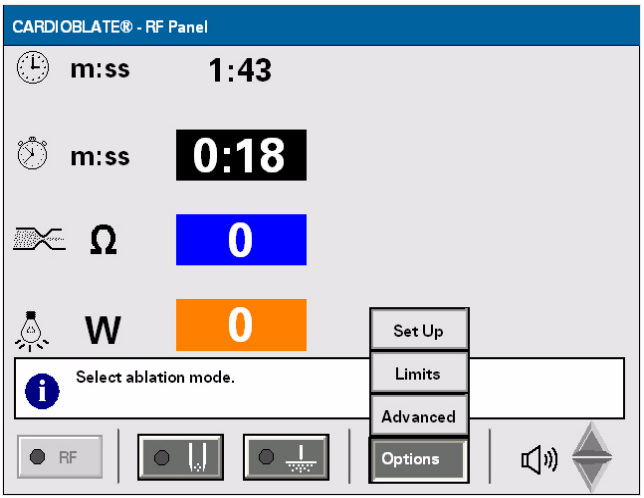
Note: English is the default language for the Medtronic Cardioblate® 68000 Generator.

To change the language option:

1. Access the Options Menu

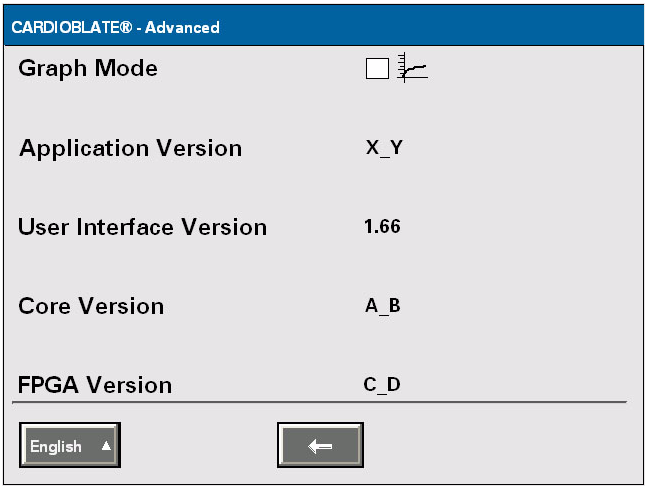
To access the Options Menu, press the Options button

located in the lower-right side of the RF panel screen.



2. Select the Advanced screen

Select the Advanced option, which will bring up the Advanced Options screen.

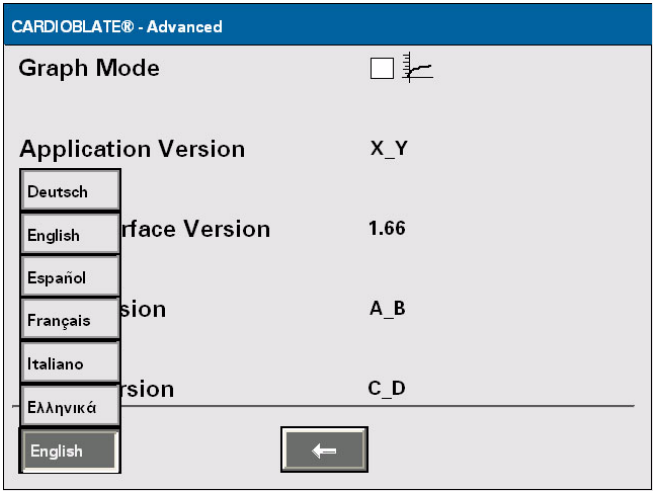


3. Select the Language button

Press the Language button located in the lower left-side of the Advanced Options screen. Select the desired language. The following languages are available for use:

- English
- German

- Spanish
- French
- Italian
- Greek



Note: At any time, the backwards arrow button can be used to return to a previous screen.

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System Description

The Medtronic® Cardioblate® Surgical Ablation System Model 68000 consists of a generator and included accessories. The surgical ablation system is designed to deliver radiofrequency (RF) energy to selected sites via a Cardioblate® surgical ablation device (hereafter referred to only as the ablation device). The generator is line-powered and is designed to be placed on a table.

The high-impact plastic generator case has a convenient carrying handle and a display screen. An easy-to-use latch mechanism secures and releases the display screen. The display screen provides users with real-time treatment information in graphical and digital formats. Message fields on the display screen also provide critical information during the treatment procedure.

The user interface includes a touch-screen that responds to gloved and ungloved touch. When the user touches a control-button icon on the screen, the system performs the function selected if no errors exist.

The user interface also provides unique audible tones to automatically notify the user of the treatment status or alert condition.

Key features include the following:

Touch screen operation – The generator parameters can be easily set and adjusted using the touch screen panel.

RF energy modes – The generator controls the amount of energy being delivered through the ablation device in one of the following energy modes:

- In **monopolar mode**, the generator monitors and controls the amount of RF energy delivered to the tissue between the ablation device and the dispersive electrode at a preselected power setpoint throughout the ablation.
- In **bipolar and enhanced bipolar modes**, the generator monitors tissue impedance and adjusts the amount of power delivered to the tissue between the active electrode jaws to create transmural lesions.
- EMG throughput is available in monopolar mode only.

Safety shutdowns – RF energy delivery stops if the operator-selected or manufacturer-programmed impedance, power, or temperature limits are exceeded. If a warning message appears, see Chapter 4, “Safety Shutdown and Troubleshooting,” for detailed information.

Package Contents

The Cardioblate® Surgical Ablation System (Model 68000) package may contain the following items (Figure 1-1):

- One Model 68000 generator
- One Model 60883 remote control foot switch
- One power cord: Model 4807
- Product literature

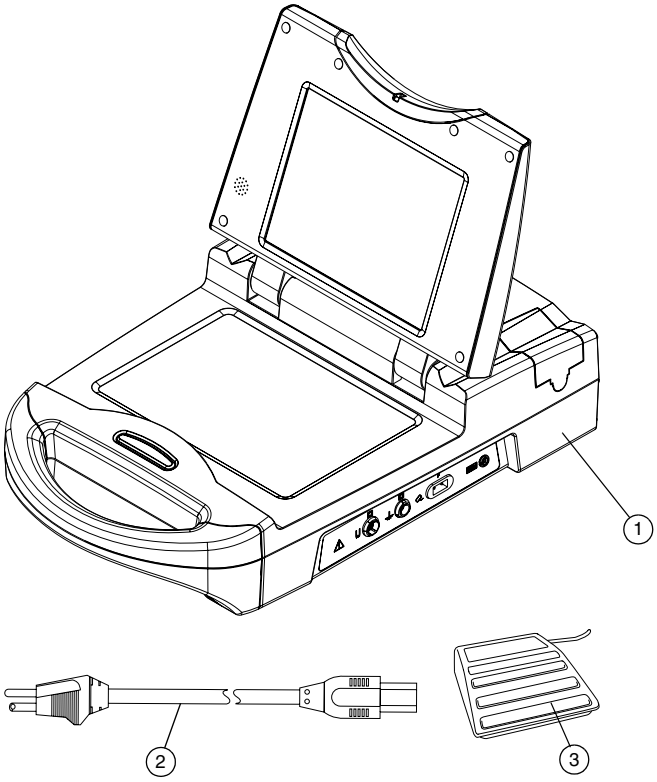

Figure 1-1. 68000 Generator

1. Model 68000 generator
2. Power cord
3. Remote control foot switch

Other Applicable Accessories

The following accessories are applicable to the Cardioblate® Surgical Ablation System but are not included in the Model 68000 package:

- Medtronic® Cardioblate® surgical ablation devices
  - Model 60813 - Cardioblate® Surgical Ablation Pen
  - Model 60814 - Cardioblate® Surgical Ablation XL Pen
  - Model 60831 - Cardioblate® Surgical Ablation BP2 Device
  - Model 60841 - Cardioblate® Surgical Ablation LP Device
  - Models 49260/49261 - Cardioblate® Gemini™ Surgical Ablation Devices
  - Medtronic released products labeled for use with the Cardioblate® 68000 Generator as an external device

  Caution: Cardioblate® bipolar device, Model 60821, cannot be used with the Cardioblate® 68000 Generator.

  Caution: Only use Medtronic® ablation devices and Medtronic recommended accessories. The safety of use with other surgical ablation devices, catheters, or accessories has not been assessed.
- Dispersive electrode with a conductive adhesive and a minimum surface area of 100 cm^2.
- Model 60889 - Medtronic® Cardioblate® Diagnostic Kit

Indications for Use

The Cardioblate® Surgical Ablation System is intended to ablate soft tissue during general surgery using radiofrequency energy.

Contraindications

The Cardioblate® Surgical Ablation System is contraindicated for patients with active endocarditis at the time of surgery.

Warnings and Precautions

General

Product literature – Do not attempt to operate the Cardioblate® Surgical Ablation System or connect the ablation device to the generator prior to completely reading and understanding the product literature for the Cardioblate® Surgical Ablation System and the ablation device.

System compatibility – Only use Medtronic ablation devices and Medtronic-recommended accessories. The safety of use with other surgical ablation devices, catheters, or accessories has not been assessed.

Single Use Devices – Medtronic ablation devices designed for use with this generator are intended for single-time use. The Cardioblate Generator has functionality to prevent the reuse of the surgical ablation devices.

Accessories – Regularly inspect and test reusable cables and accessories. Do not use any cable or accessory that appears to be damaged, and take the following precautions:

- Inspect for insulation damage, such as brittleness, cracking, thinning or bare spots.
- Replace damaged accessories.

See Chapter 2, “Generator Description,” for detailed information regarding accessories.

Electrical shock and/or burns – To avoid the risk of electrical shock and/or burns to the patient, do not touch the patient while touching the outer housing or connections on the Cardioblate® generator. Do not allow the patient to come into contact with grounded metal surfaces during RF energy delivery.

Electrostatic Discharge (ESD) is the sudden transfer or discharge of static electricity from one object to another. Human bodies can create ESD charges of up to 25,000 volts.

- Connector pins identified with the ESD warning symbol should not be touched. NO connections should be made to these connectors unless ESD precautionary procedures are followed. ESD applied to one of these connectors may cause the generator to display an error message and interrupt RF energy delivery until the message is acknowledged and/or removed.
- Precautionary procedures include the following:
  - Prevent electrostatic charge build-up (eg, air conditioning, humidification, conductive floor coverings, and nonsynthetic clothing);
  - Discharge one's body to the frame of the equipment or system, to earth, or a large metal object prior to making a contact;
  - Bond oneself by means of a wrist strap to the equipment or system, or to earth prior to making a contact.

Ablation Therapy Hazards

Lesions – The long-term effects of lesions created by RF ablation have not been established; note the following:

- Any long-term effects of lesions in proximity to the conduction system or coronary vasculature are unknown.
- The risks/benefits in asymptomatic patients have not been studied.

Artrioventricular (AV) node modification or septal accessory pathway ablation – Patients undergoing AV node modification or septal accessory pathway ablation are at risk for complete AV blockage:

- Closely monitor AV conduction after RF energy delivery

Using RF energy near implanted devices – RF energy may adversely affect implanted devices, such as pacemakers and implantable cardioverter-defibrillators (ICDs). To avoid this, do the following:

- Keep external sources of pacing and defibrillation available during ablation.

- Deactivate ICD detection during RF energy delivery.
- Exercise extreme caution when delivering ablation energy in close proximity to implanted leads.
- Perform complete implantable device testing before and after ablation.

Electrosurgery near flammable materials – The risk of igniting flammable gases or other materials is inherent in electrosurgery and cannot be eliminated by device design. Flammable agents used for cleaning or disinfecting, or as solvents of adhesives, should be allowed to evaporate before the application of high frequency surgery. There is a risk of pooling of flammable solutions under the patient or in body depressions such as the umbilicus, and in body cavities such as the vagina. Any fluid pooled in these areas should be mopped up before RF surgical equipment should be used. Attention should be called to the danger of ignition of endogenous gases. Take precautions to restrict flammable materials and substances from the electrosurgical site. Flammable materials may come in the following forms:

- Anesthetics or skin preparation agents.
- Natural chemicals produced within body cavities.
- Chemicals originating in surgical drapes or other materials.

Unintentional patient burns – To avoid unintentional burns to the patient during RF energy delivery, do the following:

- Minimize the distance between the dispersive electrode and the operating field.
- Minimize skin-to-skin contact between parts of the patient's body by covering these areas with dry gauze.
- Place monitoring electrodes as far as possible from surgical electrodes to minimize burns at the site of the monitoring electrodes.
- When using multiple ablation devices, remove those devices not actively in use from patient contact. In all cases, monitoring systems incorporating high frequency current-limiting devices are recommended.

Handling RF devices during therapy – The generator is capable of delivering significant RF energy. Do not touch the ablation electrode of the ablation device or the dispersive electrode or both electrodes on a bipolar device while operating the generator.

Equipment failure – The failure of the generator or hand piece could result in an unintended increase of output power. See Chapter 4, “Safety Shutdown and Troubleshooting,” for detailed information.

Generator Operation

High impedance – Monitor the device impedance measurement display during RF energy delivery. If abnormally high impedance is observed, examine the ablation electrode for coagulum. If coagulum is present or any irrigation opening is found to be blocked, remove coagulum or replace the ablation device prior to continuing the procedure.

If high impedance is preventing ablation from occurring, do the following:

- Check all connections.
- Check for obvious defects or misapplication of the dispersive electrode (if the monopolar device is in use).
- If a patient must be repositioned during a procedure, verify that there is proper contact between the patient and the dispersive electrode after the patient has been moved.

Low impedance – Some patients may have an abnormally low impedance between the ablation device and dispersive electrode, causing a safety shutdown. Moving the dispersive electrode to a location on the body that is farther from the device may correct this situation.

Fan – Do not obstruct the cooling fan located on the rear of the generator (Figure 2-5). Obstruction of the cooling fan could result in over-heating and device shutdown.

Cardioblate® Ablation Device Use

See Directions for Use for Cardioblate® ablation devices being used during the procedure.

Medical Environment

Line-powered equipment – Properly ground all line-powered equipment used on or in the vicinity of the patient. An ablation device connected to an RF generator constitutes a direct, low-resistance current pathway to tissue, including the myocardium.

Necessary environment – Ablation procedures should be performed only by trained personnel in a fully equipped operating room as follows:

- An emergency cardiovascular team should be available during the ablation procedure in case of a cardiovascular emergency.
- The ablation device should be used only by or under the supervision of physicians trained in cardiac surgery and experienced in surgical ablation procedures.

Generator storage temperature – If the generator has been stored at temperatures greater than 30°C or less than 15°C, allow the generator to reach room temperature or wait at least 60 minutes before use, whichever is greater.

Fluid ingress – The generator may not function correctly if the electronic circuitry or the connectors are wet; note the following:

- Do not allow any fluid or moisture into the generator or any connector or cables.
- Do not hang fluids above the generator.
- Do not immerse the cables into fluids.

Electromagnetic interference (EMI) – EMI produced by the generator during normal operation may adversely affect the performance of other equipment.

Please refer to applicable standards for additional information.

Adverse Events

The potential adverse events related to the use of ablation systems include, but are not limited to, the following:

- Death
- Cardiac tamponade
- Cerebrovascular accident
- Transient ischemic attack
- Myocardial infarction
- Coronary sinus perforation
- Ventricular fibrillation
- Atrial arrhythmia
- Coronary artery spasm
- Valvular insufficiency
- Pericardial effusion
- Pericarditis
- Pleural effusion
- Atrial lead dislodgment
- Hypotension
- High creatinine phosphokinease (CPK)
- Thromboembolism
- Nerve or blood vessel injury
- Phrenic nerve injury
- Unintended SA or AV nodal dysfunction requiring pacemaker implantation
- Unintentional burns
- Pulmonary vein stenosis
- Esophageal injury
- Tissue perforation
- Valve leaflet damage

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Components

Introduction

The Model 68000 Cardioblate® Generator (Figure 2-1) is lightweight and portable with state of the art electronics and design features that provide the user with a safe and effective Cardioblate® Surgical Ablation System.

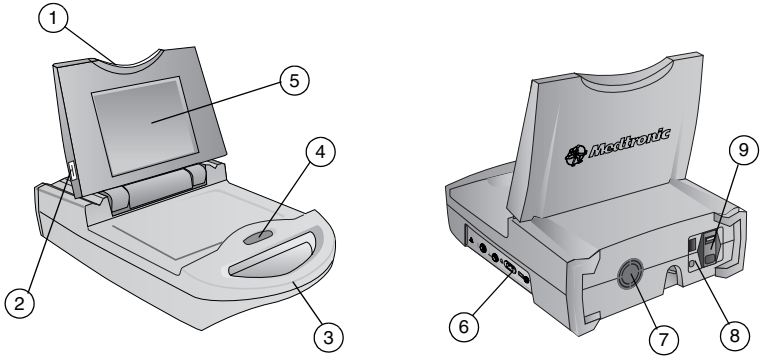

Figure 2-1. Model 68000 Cardioblate® Generator Case

The following are the basic user components:

1. Bezel Light Panel
2. USB Port
3. Transport Handle
4. Display Release Button
5. Display Screen
6. Therapy Connector Panel
7. Cooling Fan
8. Optional Device Connector
9. AC Power Panel

At the top of the cover assembly there is a bezel light panel with three LEDs: two blue and one green. When the center green LED is lit, it indicates that the AC power is on. When the two blue LEDs are flashing, the generator software is performing its self-test. When the blue LEDs are solid, RF energy is being applied and a lesion is in progress.

Displays, Connectors, and Controls

Right Side Panel

The applicable Medtronic® Cardioblate® surgical ablation devices and the dispersive electrode cable can be connected to the Cardioblate® Generator via the therapy connector panel located on the right side of the generator.

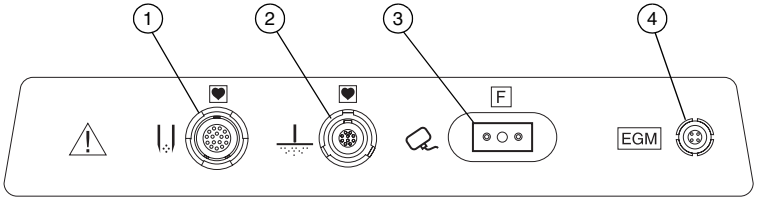

Figure 2-2. Right Side Therapy Connector Panel

1. **Cardioblate® Bipolar ablation device connector**
   This multipin connector provides the interface to a bipolar ablation device.

2. **Cardioblate® Monopolar ablation device connector**
   This multipin connector provides the interface to a monopolar ablation device.

3. **Dispersive electrode connector**
   This connector provides the interface to the dispersive electrode via the dispersive electrode cable.

4. **EGM Connection** EGM
   This multipin connector provides the interface to EGM monitoring equipment.

Left Side Panel

On the left side panel there is a Universal Serial Bus (USB) port, which is intended for Medtronic field service personnel. It allows the field service personnel to connect a USB flash memory device to the generator. The flash memory device can be used for uploading application updates and for downloading stored data from the generator.

The Cardioblate® Diagnostic Kit (Model 60889) application is also loaded via this USB port. Refer to the product literature for detailed instructions.

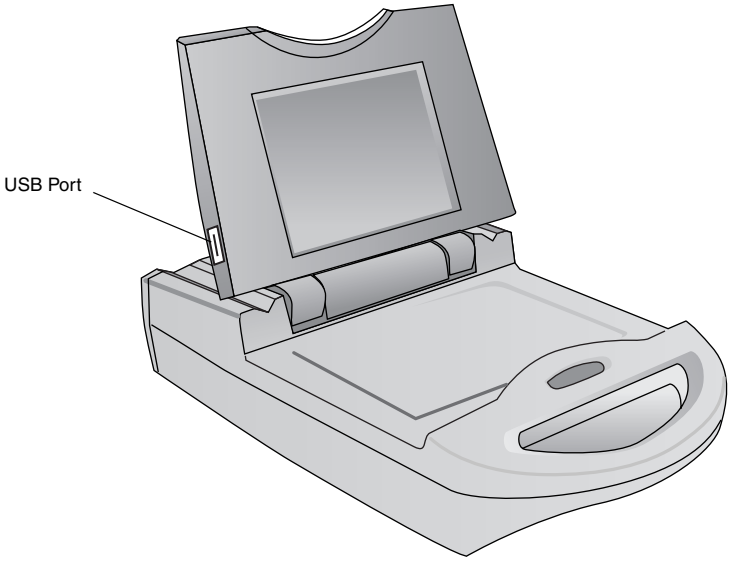

Figure 2-3. USB Port location

Touch Screen Display

Display Screen

The color (640x480 pixels), liquid-crystal-display (LCD) screen closes into the case for storage and flips open on a hinge for use. The display screen provides users with real-time treatment information in graphical and digital formats. The screen's hinge allows adjustment for different viewing angles. When the generator is on, the screen also remains on at all times and in all positions; there is no “screen saver” mode. Figure 2-4 details the touch screen display present upon start-up.

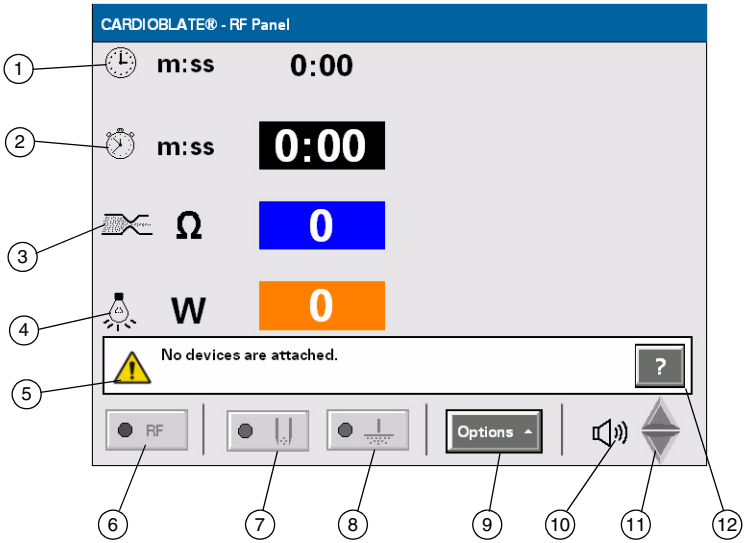

Figure 2-4. Touch screen display

1. **Total RF time**
   The cumulative amount of RF energy delivery time, since the generator was powered ON, is displayed. The counter resets to 0:00 when the generator is powered OFF and then ON.

2. **RF timer measurement display**
   This displays the duration (minutes:seconds) of each RF delivery cycle. The display automatically resets to 0:00 when the RF energy delivery begins and measures until RF energy delivery stops. The elapsed time of the delivered RF cycle is displayed until the next RF cycle begins.

3. **Impedance measurement display**
   This displays the measured impedance (Ω). For the monopolar device, this is between the ablation electrode of the ablation device and the dispersive electrode during the delivery of RF energy. For the bipolar device, this is between the jaws of the bipolar device during delivery of RF energy.

4. **RF power measurement display**
   This displays the amount of RF power (in watts) being delivered.

5. **Message Box**
   This displays text messages regarding generator status, including system warnings.

6. **RF energy button**
   The RF button both activates and deactivates the delivery of RF energy to the selected device.

7. **Bipolar button**
   The bipolar button selects the bipolar mode. This button can only be selected when a bipolar device is attached.The selected button remains active while the bipolar mode is in effect.

8. **Monopolar button**
   The monopolar button selects the monopolar mode. This button can only be selected when a monopolar device is attached. The selected button remains active while the monopolar mode is in effect.

9. **Options**
   The options button accesses the options menu. For further information on options, refer to “Options” on page 3-17.

10. **Speaker Volume Level**
    The speaker volume level icon is the readout for the audio control buttons. The number of curved lines increase and decrease with the volume settings. There are five volume levels; the lowest level is still audible and there is no OFF setting.

11. **Audio control**
    The audio control buttons adjust speaker volume.

12. **Information button**
    The information button provides details to the user regarding possible causes and solutions for device errors.

Rear Panel

The rear panel (Figure 2-5) contains the AC power, equipotential ground, and optional device connections. The AC power connection includes a power-entry plug assembly with an ON/OFF power switch and two power fuses.

A recessed, equipotential grounding terminal provides convenient access for grounding the generator with another electronic devices. There is also a connector for the cable to the optional Medtronic foot switch Model 60883 that activates the radio frequency delivery system.

The rear panel USB communications port is to be used only by Medtronic field service personnel. The port is secured against unauthorized use.

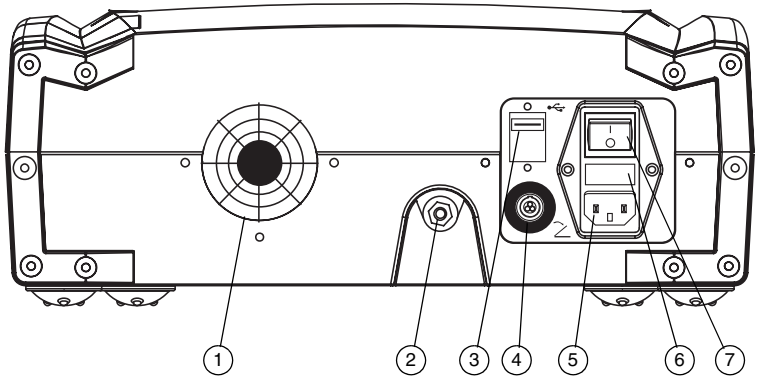

Figure 2-5. Rear panel

1. **Fan**
   Provides constant air flow to cool electronics when power is on.
   Do not obstruct the cooling fan. Obstruction of the fan could result in overheating and device shutdown.

2. **Equipotential ground post**
   Provides common electrical ground for other electronic devices being used during the procedure.

3. **USB Port**
   Connection to USB cable for external digital device communication. This security-protected connector is for Medtronic use only.

4. **Remote control foot switch connector**
   This connector provides the interface to the remote control foot switch.

5. **Power entry connector**
   This connector provides the interface to AC line power via the power cord.

6. **Fuse**
   This housing contains two field-replaceable 3.15 Amp. slow-blow fuses. Refer to “Replacing the Generator Fuse” on page 5-2.

7. **ON/OFF Switch**

Remote Foot Switch

The Model 60883 Remote Foot Switch (Figure 2-6) is an optional remote control device that connects to the rear panel of the Model 68000 Cardioblate® Generator. When the remote foot switch is properly connected to the generator, the user can press the foot switch to start RF energy delivery. To stop the RF energy delivery, the user releases the remote foot switch.

The connector end of the remote foot switch has an easy-to-use connector release mechanism. To disconnect the cable from the generator, pull back on the textured grip ring to release the lock before removing the connector.

Figure 2-6. Model 60883 Remote Foot Switch
Table 2-1.

Audible Tones

Table 2-2. Model 68000 audible tones

Generator tone	Meaning
Two tones at regularly spaced intervals	System error that may require a re-boot
Regularly spaced single medium-pitch beeps	RF energy is being delivered to the monopolar device
Regularly spaced dual medium-pitch beeps	RF energy is being delivered to the bipolar device
Three low-pitched beeps	An error condition has caused a safety shutdown
Continuous medium-pitch tone	Transmurality algorithm is complete

Specifications

Model 68000 Generator

Table 2-3. Model 68000 generator specifications

Physical characteristics	
Dimensions	55 x 35 x 14 cm (21.8 x 13.8 x 5.5 in)
Weight	9.5 kg (21 lbs)
Power requirement	100 - 240 VAC, 270VA, 50 - 60 Hz
Fuse protection	Two 250 V, 3.15 Amp. slow-blow fuses (user accessible)

Table 2-3. Model 68000 generator specifications (continued)

Functional characteristics	
RF power output setpoint/limit (Monopolar Mode)	Range: 1 to 50 W Increment: 1 W Accuracy: ± 10% or 3 W, whichever is greater (Impedance ≥ 30 Ω and Impedance ≤ 400Ω) Accuracy: ± 20% or 3 W, whichever is greater (Impedance < 30 Ω or Impedance > 400 Ω)
RF power output setpoint/limit (Bipolar Mode)	Range: 15 to 40 W (automatically varying) Increment: 5 W Accuracy: ± 10% or 3 W, whichever is greater (Impedance ≥ 30 Ω and Impedance ≤ 400 Ω) Accuracy: ± 20% or 2 W, whichever is greater (Impedance < 30 Ω or Impedance > 400 Ω)
RF power output setpoint/limit (Enhanced Bipolar Mode)	Range: 15 to 55 W (automatically varying) Increment: 5 to 10 W, varying Accuracy: ± 10% or 3 W, whichever is greater (Impedance ≥ 30 Ω and Impedance ≤ 400 Ω) Accuracy: ± 20% or 2 W, whichever is greater (Impedance ≤ 30 Ω or Impedance > 400 Ω)
RF power output frequency	473 ± 5 kHz
Maximum RF voltage, between electrodes	180 Vrms ± 10%
Maximum RF Current	2A ± 150 mA
Impedance limits	Range: 12 to 600 Ω Increment: 5 Ω Accuracy: ± 15% for 20 to 500 Ω Accuracy: ± 20% or 5 Ω (whichever is greater) for 12 to 20 Ω and 500 to 600 Ω
RF timer limit (Monopolar Mode)	Range: 1 second to 2 minutes, inclusive Increment: 1 second Accuracy: ± 1% or 1 second, whichever is greater
RF timer limit (Bipolar Mode)	Range: 2 to 40 seconds (automatically controlled)

Table 2-3. Model 68000 generator specifications (continued)

RF timer limit (Enhanced Bipolar Mode)	Range: 2 to 45 seconds (automatically controlled)	
Default Settings		
RF power	Monopolar mode: 25 W Bipolar mode: NA	
Impedance (Monopolar Mode)	Maximum: 500 Ω	Minimum: 12 Ω
Impedance (Bipolar Mode)	Maximum: 500 Ω	Minimum: 12 Ω
RF timer	Monopolar mode: 2 minutes	
Temperature and humidity information		
Operating temperature and humidity	10 to 40°C, 80% relative humidity	
Storage/shipping temperature and humidity	-40 to 66°C, 95% relative humidity	
Rear panel connectors		
Fused power connector	3-prong fused mains (AC) power receptacle	
Ground post	Equipotential ground post	
Remote control foot switch connector	3-pin Lemo®[a] receptacle	
Side panel connectors		
Dispersive electrode	2-pin return electrode	
Cardioblate® monopolar ablation device	10-pin Lemo®	
Cardioblate® bipolar ablation device	16-pin Lemo®	
EGM connector	4-pin Lemo® receptacle	
Safety information	IEC 60601-1, Class 1, Type CF, IPX0, no sterilization, equipment not suitable for use in the presence of a flammable anaesthetic mixture with air, oxygen, or nitrous oxide, continuous operation UL 60601-1: With respect to electrical shock, fire, and mechanical hazards, only in accordance with UL 60601-1	

[a] Lemo® is a registered trademark of Lemo USA, Inc.

Accessories

Table 2-4. Accessory specifications

Medtronic® Model 60883 remote control foot switch	
Dimensions	13 x 15 x 5 cm (5 x 6 x 2 in)
Cable length	472 cm (15.4 ft)
Weight	645 g (1.42 lbs)
Connector	3-pin Lemo®
Environmental conditions	IP 68, water resistant
Medtronic® Model 4807, 4808, or 4809 power cord	
Length	3 m (nominal) (10 ft)
Connectors	3-pin hospital-grade safety plug

Output Power Diagrams

The following diagrams (Figure 2-7 through Figure 2-9) show the output power versus load impedance at three power setpoints: 25 W, 50 W, and 100 W at cold and warm operating temperatures. The generator was tested at fixed impedances using noninductive resistors.

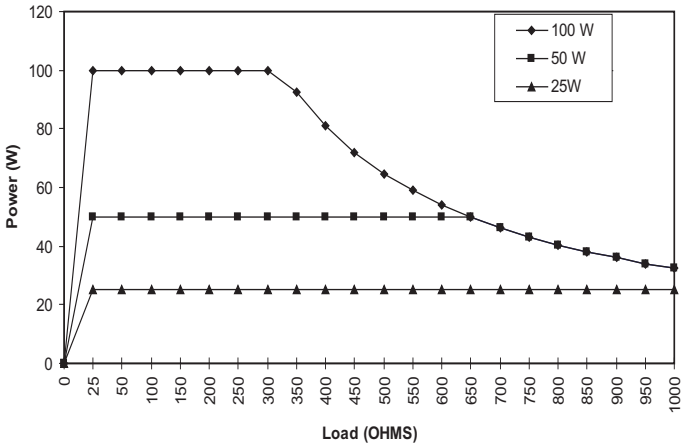

Figure 2-7. Monopolar Load Curves

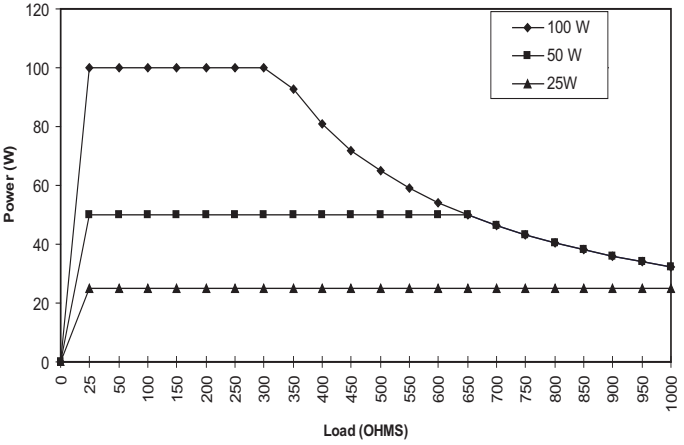

Figure 2-8. Bipolar Load Curves

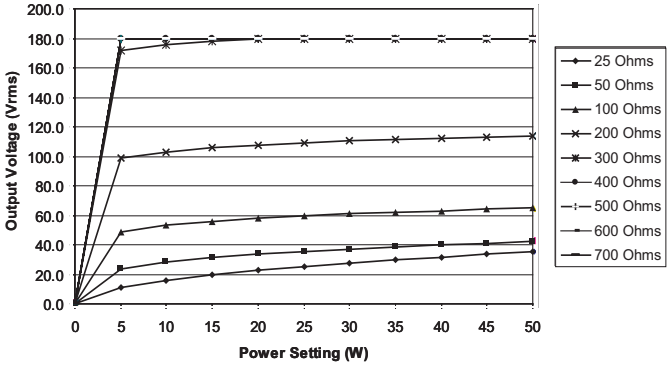

Figure 2-9. Voltage Curve

Electromagnetic Emissions and Immunity Declaration (EN60601-1-2)

Table 2-5. Electromagnetic Emissions

The **Model 68000 Generator** is intended for use in the electromagnetic environment specified below. The customer or the user of the generator should ensure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
Radio-frequency (RF) emissions CISPR 11	Group 2	The Model 68000 must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.
RF emissions CISPR 11	Class A	The Model 68000 is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC/EN 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC/EN 61000-3-3	Complies	

Table 2-6. Electromagnetic Immunity

The **Model 68000 Generator** is intended for use in the electromagnetic environment specified below. The customer or the user of the generator should ensure that it is used in such an environment.			
Immunity Test	**EN 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment – Guidance**
Electrostatic discharge (ESD): IEC/EN 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst: IEC/EN 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.

Table 2-6. Electromagnetic Immunity (continued)

Surge: IEC/EN 61000-4-5	±1 kV line(s) to line(s) ±2 kV lines(s) to Earth	±1 kV line(s) to line(s) ±2 kV lines(s) to Earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines: IEC/EN 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 25 sec.	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles	Mains power quality should be that of a typical commercial or hospital environment. If the user of the device requires continued operation during power mains interruptions, it is recommended that the device be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field: IEC/EN 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Note: U_T is the A.C. mains voltage prior to application of the test level.			

Table 2-7. Electromagnetic Immunity, IEC 60601-1-2: 2001 Table 204

Immunity Test	**EN 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment–Guidance**
Portable and mobile RF communications equipment should be used no closer to any part of the Model 68000, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.			
			Recommended separation distance
Conducted RF IEC/EN 61000-4-6	3 V_{rms} 150 kHz to 80 MHz	3 V_{rms}	$d = 1.2\sqrt{P}$
Radiated RF IEC/EN 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz

Table 2-7. Electromagnetic Immunity, IEC 60601-1-2: 2001 Table 204 (continued)

Where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol:
Notes: ▪ At 80 MHz and 800 MHz, the higher frequency range applies. ▪ These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Model 68000 is used exceeds the applicable RF compliance level above, the Model 68000 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the device.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Table 2-8. Recommended separation distances between portable and mobile radio frequency (RF) communication equipment and the Model 68000 Generator. IEC/EN 60601-1-2: 2001 Table 206

The **Model 68000 Generator** is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the generator can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the generator as recommended below, according to the maximum output power or the communications equipment.

Rated maximum output power of Transmitter (W)	**Separation distance according to frequency of transmitter (m)**		
	150 kHz to 80 MHz	**80 MHz to 800 MHz**	**800 MHz to 2.5 GHz**
	$d = 1.2\sqrt{P}$	$d = 1.2\sqrt{P}$	$d = 2.3\sqrt{P}$
0.01	0.35	0.12	0.23
0.1	1.1	0.38	0.73
1	3.5	1.2	2.3
10	11	3.8	7.3
100	35	12	23

Table 2-8. Recommended separation distances between portable and mobile radio frequency (RF) communication equipment and the Model 68000 Generator. IEC/EN 60601-1-2: 2001 Table 206 (continued)

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.
Notes: ▪ At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. ▪ These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.
Cautions: ▪ Do not use non-Medtronic components with Medtronic in-line-powered external devices. The use of non-Medtronic components may result in damage to Medtronic components, increased emissions, or decreased electromagnetic immunity of the Medtronic devices or systems. ▪ Do not use Medtronic in-line-powered external devices adjacent to, or stacked with, other electronic devices. Using Medtronic devices in these configurations may result in decreased electromagnetic immunity of the Medtronic devices or systems.
RF Cable: The Medtronic® Cardioblate® surgical ablation devices' cable length is approximately 3 m in length.

Applicable Standards

IEC 60601-1 IEC 60601-1-AM1 IEC 60601-1-AM2	Class 1, Type CF, ordinary equipment, no sterilization, benign environment, continuous mode of operation, applied part specifically designed for contact directly with the heart
IEC 60601-1-2	Electromagnetic compatibility
IEC 60601-2-2	Medical electrical equipment - Part 2: Particular requirements for the safety of high-frequency surgical equipment
EN 60601-1-4	Medical electrical equipment - Part 1: General requirements for safety - 4. collateral standard: programmable electrical medical systems
UL 60601-1	Grounded construction, ordinary connection
FCC Part 18	FCC standard for EMI/EMC requirements

This equipment has been tested and found to comply with the limits for medical devices to IEC 60601-1-2 [or EN 60601-1-2 or Medical Device Directive 93/42/EEC]. This testing shows the device provides reasonable protection against harmful interference in a typical medical installation. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to other devices or is negatively impacted by other devices, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the devices.
- Increase the separation between the devices.
- Connect the equipment to an outlet on a different circuit.
- Consult the manufacturer or field service technician for help.

Generator Operation 3

Quick Reference Guide 3-2

Selecting and Attaching a Dispersive Electrode 3-3

Preparing and Powering Up the Generator 3-4

Connecting a Cardioblate® Ablation Device 3-6

Verifying Generator Recognition of Attached Devices 3-8

Disconnecting the Cardioblate® Ablation Devices 3-9

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Quick Reference Guide

A quick reference guide is located on the surface of the generator, under the display screen as shown in Figure 3-1. Detailed steps regarding setup and operation are on the following pages. Refer to the ablation device Instructions for Use for specific information on device use.

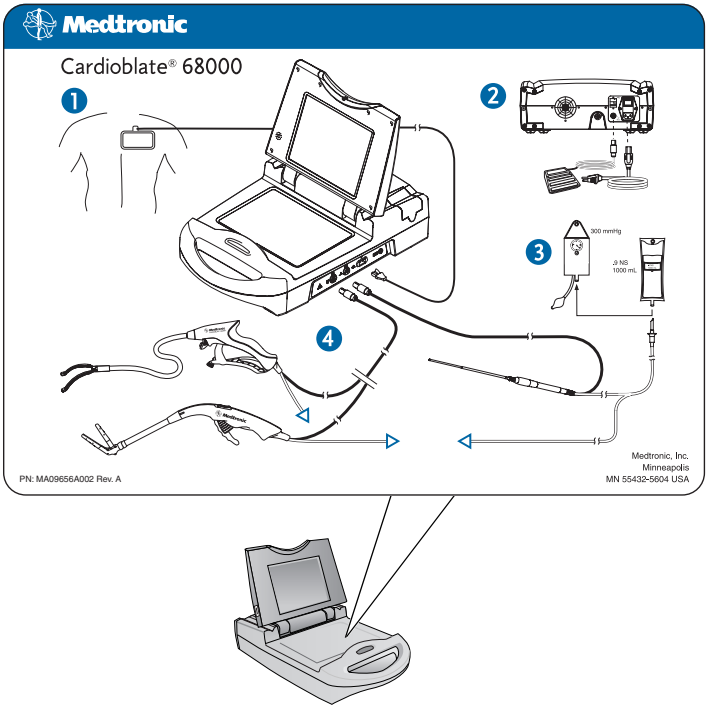


Figure 3-1. Quick Reference Guide

1. Attach the dispersive electrode.
2. Plug in the power cord and foot switch.
3. Set up saline irrigation.
4. Attach devices to the generator after the self-test is complete.

Selecting and Attaching a Dispersive Electrode

Selecting a Dispersive Electrode and Application Site

Note: A dispersive electrode is used only with a monopolar device.

1. Select a dispersive electrode with the following characteristics:
   - The dispersive electrode must have a conductive adhesive backing and a minimum surface area of 100 cm^2.
   - The dispersive electrode must meet or exceed American National Standards Institute (ANSI) and Association for the Advancement of Medical Instrumentation (AAMI) requirements.

   Refer to the product literature packaged with the dispersive electrode for additional information on the use of the dispersive electrode.
2. Select an application site for the dispersive electrode that allows the entire area of the dispersive electrode to adhere to the patient's body and is as close to the heart as possible. The recommended sites are the patient's back, mid-back, or buttocks (Figure 3-2).

   Caution: Place electrocardiogram (ECG) electrodes and other monitoring probes as far away as possible from the ablation site and the attached dispersive electrode to reduce the risk of burns.

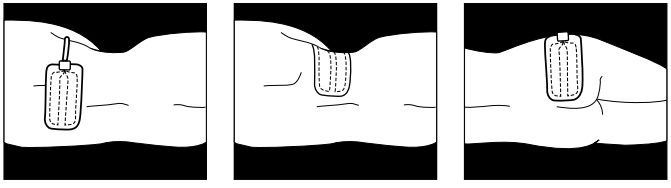


Figure 3-2. Dispersive electrode application site

Attaching the Dispersive Electrode

1. Shave, clean, and dry the application site.
2. Apply the dispersive electrode to the application site according to the instructions in the dispersive electrode manufacturer's product literature.
3. Use antistatic (nonconductive) sheeting to keep the patient from coming into contact with metal parts that are grounded or can act as a ground (eg, the operating table, supports).
4. Place dry gauze on the patient in areas of potential skin-to-skin contact (eg, between arms and torso).

   Caution: Ensure the entire dispersive electrode is attached to the patient's body.

Preparing and Powering Up the Generator

Setting Up the Generator

1. Place the RF generator on a suitable table that does not obstruct the rear-panel cooling fan air flow. Then, press the display release button and position the display screen.

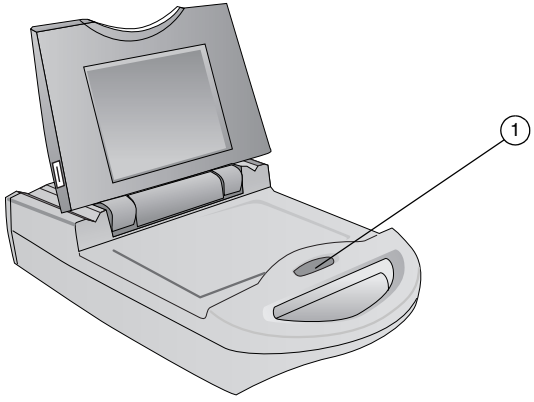


Figure 3-3. Open Display Screen

2. Verify that all of the components are present. See "Package Contents" on page 1-3.
3. Inspect the components. If any component is damaged, contact your local Medtronic representative.

Connecting Cables to the Generator

Note: Refer to “Displays, Connectors, and Controls” on page 2-3 for connector locations on the generator.

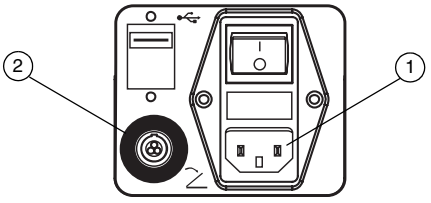


Figure 3-4. AC Power Panel and Optional Device Connectors

1. Connect the power cord:
   a. Plug the power cord into the power entry connector on the back of the generator (see Figure 3-4).
   b. Plug the power cord into an AC outlet.
2. Connect the remote control foot switch to the generator:
   a. Align the foot switch cable connector to the foot switch connector on the back of the generator (see Figure 3-4).
   b. Insert the foot switch connector until the metal locking ring clicks.

   Note: To disconnect the foot switch from the generator, pull back on the textured grip ring to release the lock before removing the connector.
3. Monopolar Devices Only: Dispersive electrodes are required for operation with monopolar devices. Dispersive electrodes have two styles — with or without cables pre-attached. For dispersive electrodes with cables attached, simply connect the cable end to the generator. If the dispersive electrode does not have a pre-attached cable, use a separate cable and connect one end to the dispersive electrode and the other end to the generator.

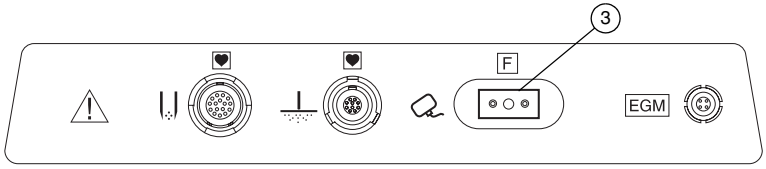


Figure 3-5. Therapy Connector Panel

Powering Up the Generator

1. Press the AC power button up on the rear panel once to power up the generator.

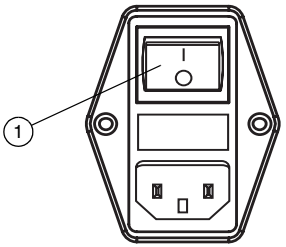


Figure 3-6. AC Power Panel

2. Once the generator completes its self-test, the RF panel screen will appear.

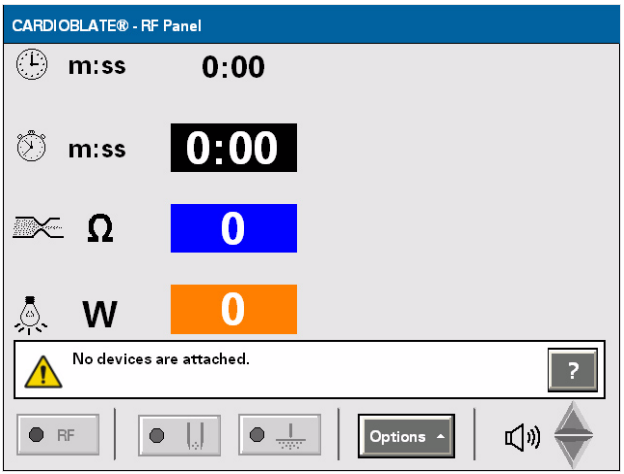


Figure 3-7. RF Panel Screen

Connecting a Cardioblate® Ablation Device

Note: Refer to the product literature supplied with the ablation device for further information on its use.

Note: Ensure the generator is turned on and the self-test completed prior to attaching ablation devices.

Note: Do not attempt to reuse an ablation device with this generator. If the ablation device has been previously used, the error message, "**Device Error. Replace Device**." will appear. Replace the ablation device before proceeding.

Note: If the ablation device is not a Medtronic ablation device designed for use with this system, the error message "**Device Error. Invalid device attached**." will appear until the device is replaced with a Medtronic ablation device.

Connecting the Monopolar Ablation Device

1. Orient the monopolar ablation device plug with the arrow pointing up.
2. Insert the multipin connector of the monopolar ablation device into the monopolar device port on the right side of the generator until it locks into place (Figure 3-8). Do not force the connection.

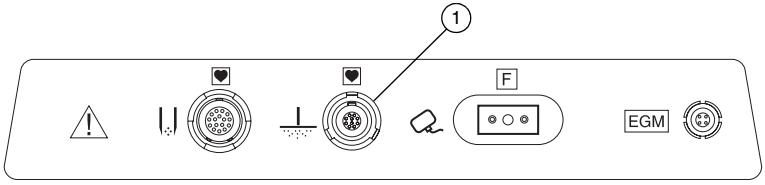


Figure 3-8. Monopolar Device Port

Note: After the device is connected and recognized, the Monopolar Button will become active (dark grey).

Note: An error message will appear if the dispersive electrode is not attached and recognized.

Connecting the Bipolar Ablation Device

1. Orient the bipolar ablation device plug with the arrow pointing up.
2. Insert the multipin connector of the bipolar ablation device into the bipolar device port on the right side of the generator until it locks into place (Figure 3-9). Do not force the connection.

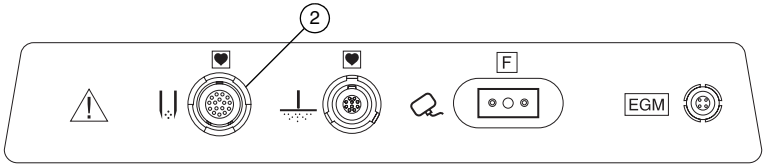


Figure 3-9. Bipolar Device Port

Note: After the device is connected and recognized, the Bipolar button will become active (dark grey).

Verifying Generator Recognition of Attached Devices

1. Press the Options button on the Generator RF Panel.
2. Press the Setup button. The Setup and Connection Status screen appears (Figure 3-10).
3. Verify that the components attached to the generator are recognized. If the component is recognized, a checkmark will appear on the screen in beside the device icon. If the components are not recognized, a red arrow will appear on the screen pointing to the generator icon.
4. Press the backwards arrow button ← to return to the main RF Panel screen.

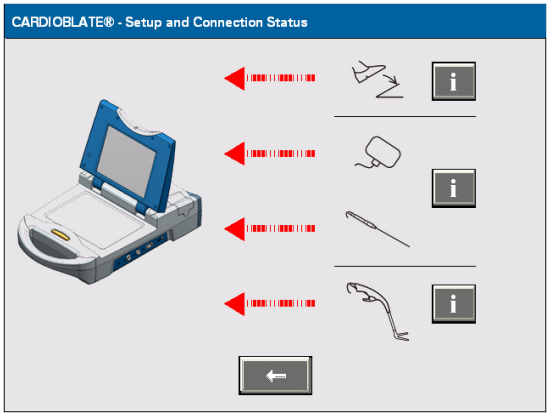


Figure 3-10. Setup and Connection Status screen, devices not attached or recognized

Disconnecting the Cardioblate® Ablation Devices

To disconnect the devices from the generator, pull back on the grip ring to release the lock before removing the device.

Setting the RF Energy Mode and Parameters

The generator can control the amount of energy being delivered through an ablation device in two modes.

- In **monopolar mode**, the generator monitors and controls the amount of RF energy delivered to the tissue between the ablation device and the dispersive electrode at a preselected power setpoint throughout the ablation.
- In **bipolar mode**, the generator monitors tissue impedance and adjusts the amount of power delivered to the tissue between the active electrode jaws to create transmural lesions.

Monopolar Mode Selection and Use

Selecting the Monopolar Mode

Select the Monopolar Button

Using the touch screen buttons located at the lower-left corner of the RF Panel display, select the Monopolar button . When the monopolar mode is selected, the Monopolar button will appear depressed and grey (Figure 3-11).

1. The display screen will show the limit and setpoint values from the previous use of the generator.
2. Review the displayed values for RF power setpoint and RF timer limit. Adjust the values as necessary.

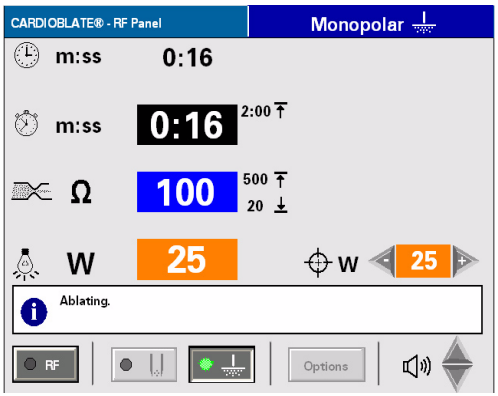


Figure 3-11. RF Panel in Monopolar Mode

Adjusting the Setpoint Values and Limits in the Monopolar Mode

Refer to Table 3-1 for a more detailed description of adjustable parameter functions in monopolar mode.

1. Adjust the RF power setpoint in 1 W increments by pressing the ▶ button to increase or ◀ button to decrease the value (Figure 3-11).

Caution: The selected output power should be as low as possible for the intended purpose. Refer to the device product literature for detailed instructions. A low output power may be useful for the following situations:

- Ablation of targets where there is risk of collateral damage to structures in close proximity, eg, ablation of a septal pathway very close to the AV node or esophageal damage.
- Ablation in locations where blood flow may be limited postablation.
- Ablation in patients who may have unusually thin cardiac walls.

Table 3-1. Operational modes and adjustable parameter functions

Mode	Parameter and function	Safety shutdown condition
Monopolar mode	**RF power setpoint** is the wattage of RF energy delivery.	If the measured power varies from the setpoint, the generator will stop RF energy delivery.
	Impedance limit is automatically set.	If the measured impedance is outside the limits, the generator will stop RF energy delivery.
	RF timer limit is the maximum amount of time in an RF energy delivery cycle.	If set time is exceeded, the generator will stop RF energy delivery.

Adjusting the RF Timer Limits in the Monopolar Mode

1. Access the Limits menu by pressing the Options button on the RF Panel screen and then the Limits button.
2. On the Limits screen, adjust the RF timer in 1-second increments by pressing + to increase or - to decrease the value.

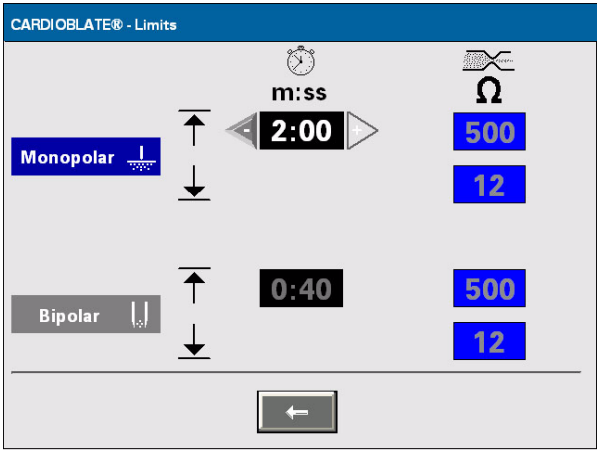


Figure 3-12. Limits screen

3. Verify the parameters are set properly before depressing the remote control foot switch or pressing the RF button RF to deliver energy.

Note: The RF Timer Limits can be changed at any point during the procedure as long as RF energy is not active.

Delivering Radiofrequency (RF) Energy in the Monopolar Mode

Caution: If there are any concerns regarding the safety or efficacy or the equipment, do not deliver RF energy. Contact your local Medtronic representative.

Note: Refer to the product literature for ablation device instructions prior to use.

1. Select the monopolar mode by pressing the appropriate button on the touch screen, and verify that the appropriate device is active.

   Note: Monopolar mode can only be selected if the monopolar device is attached and recognized by the generator.

   Note: RF energy can only be delivered to one device at a time.
2. To deliver RF energy, either press and hold the remote control foot switch or press the RF button

on the touch screen. RF energy is delivered through the monopolar ablation device.

   Delivery of RF energy is indicated by:

   - The light panel illuminating blue.
   - The message box displays “Ablating.”
   - The generator beeping. While in monopolar mode, the generator will beep once per second.

   The touch screen display shows the ablation time, total accumulated RF time, impedance, and power during ablation.

Caution: Accidental or unintentional activation of the foot switch may cause RF energy to be delivered.

3. To change the power, timer setpoint values, and limits, see “Adjusting the Setpoint Values and Limits in the Monopolar Mode” on page 3-10, with the exception noted below.

Note: During RF energy delivery in monopolar mode, the or buttons must be pressed repeatedly to adjust values.

Note: Device selection cannot be changed during the delivery of RF energy.

4. RF energy delivery will stop when the RF timer limit is reached or the user chooses to end RF energy delivery. To stop RF energy delivery before the timer reaches the limit, release the foot switch or press the RF button RF.

Note: To deliver RF energy, either press and hold the remote control foot switch or press the RF button RF on the touch screen. If the remote control foot switch is used to deliver RF power and the RF button RF is pressed to cease the delivery of RF power, the foot switch must be released before RF power can be delivered again.

Note: RF energy delivery will stop if a setpoint or limit is exceeded, causing a safety shutdown. An error message will appear in the message box. Press the Information Button i for more information. For information about safety shutdown messages, see “Safety Shutdown Messages” in Chapter 4.

5. When RF energy delivery ends, the generator will return to standby as shown in Figure 3-13.

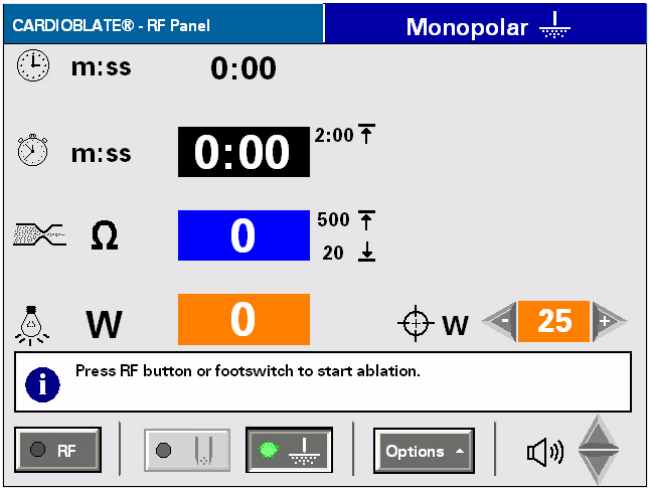
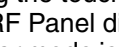


Figure 3-13. RF Panel standby mode

Bipolar Mode Selection and Use

Selecting the Bipolar Mode

Select the Bipolar Button

Using the touch screen buttons located at the lower-left corner of the RF Panel display, select the Bipolar button  . When the bipolar mode is selected, the Bipolar button will appear depressed and dark grey.

1. The values for RF power setpoint and limits, impedance limit, and RF timer limit will be adjusted automatically.

Refer to Table 3-2 for a more detailed description of adjustable parameter functions in bipolar mode.

Table 3-2. Operational modes and adjustable parameter functions

Mode	Parameter and function	Safety shutdown condition
Bipolar mode	**RF power setpoint and limit** are automatically set.	If the measured power varies from the algorithm setpoint, the generator will stop RF energy delivery.
	Impedance limit is automatically set.	If the measured impedance is outside the limits, the generator will stop RF energy delivery.
	RF timer limit is automatically set.	If maximum time is exceeded, generator will stop RF energy delivery.

Delivering Radiofrequency (RF) Energy in the Bipolar Mode

Caution: If there are any concerns regarding the safety or efficacy or the equipment, do not deliver RF energy. Contact your local Medtronic representative.

Note: Refer to the product literature for ablation device instructions prior to use.

1. Select the bipolar mode by pressing the appropriate button on the touch screen, and verify that the appropriate device is active.

Note: Bipolar mode can only be selected if a bipolar device is attached and recognized by the generator.

Note: RF energy can only be delivered to one device at a time.

2. To deliver RF energy, either press and hold the remote control foot switch or press the RF button on the touch screen. RF energy is delivered through the bipolar ablation device.

   Delivery of RF energy is indicated by:

   - The light panel illuminating blue.
   - The message box displays “Ablating.”
   - The generator beeping. While in bipolar mode, the generator will beep twice per second.

   The screen shows the ablation time, total accumulated RF time, impedance, and power during ablation.

Caution: Accidental or unintentional activation of the foot switch may cause RF energy to be delivered.

Note: Device selection cannot be changed during the delivery of RF energy.

3. RF energy delivery will stop when the RF timer limit is reached or the user chooses to end RF energy delivery. To stop RF energy delivery before the timer reaches the limit, release the foot switch or press the RF button .

Note: To deliver RF energy with a BP2 or LP device, either press and hold the remote control foot switch or press the RF button on the touch screen. If the remote control foot switch is used to deliver RF power and the RF button is pressed to cease the delivery of RF power, the foot switch must be released before RF power can be delivered again.

Note: Achievement of a transmural lesion in the bipolar mode is indicated by the generator tone changing from a beeping to a steady tone and “Transmurality reached. Power is ON.” appearing on the screen (Figure 3-14). The green transmurality symbol will also appear next to the power output. RF energy will continue until the surgeon stops ablating. To stop RF energy, release the foot switch or press the RF button .

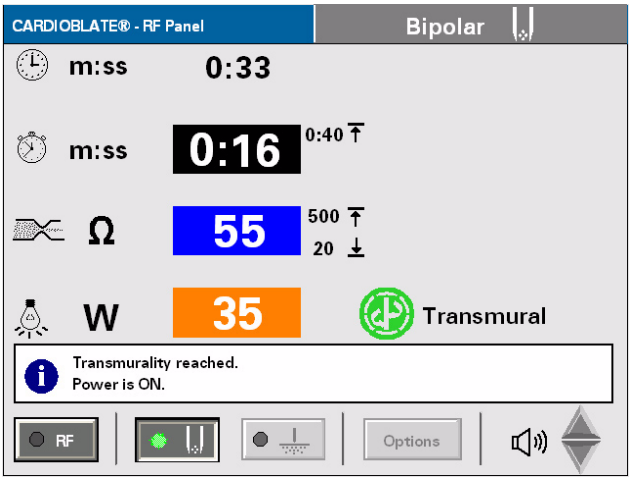


Figure 3-14. Transmurality Reached

RF energy delivery will also stop if a setpoint or limit is exceeded, causing a safety shutdown. For information about safety shutdown messages, see “Safety Shutdown Messages” in Chapter 4.

4. When RF energy delivery ends, the generator will return to standby.

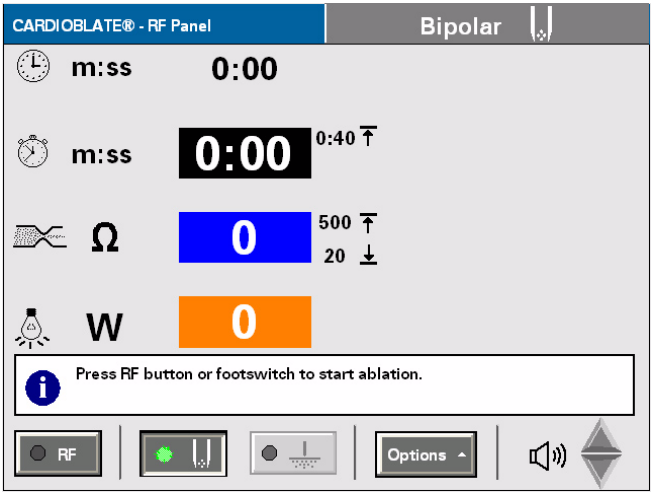


Figure 3-15. RF Panel standby mode

Options

The Options Menu provides user-friendly instructions for setting up the device and defining limits, and includes advanced features such as the Graph Mode. Software version information can also be found in the Options Menu.

Options Menu

To access the options menu, press the Options button Options located in the lower-right side of the RF panel screen to access the Set Up, Limits, and Advanced screens.

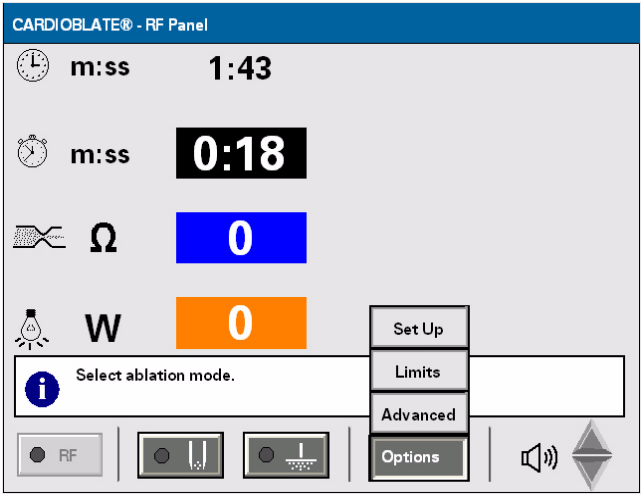


Figure 3-16. Options Menu

Note: At any time the backwards arrow button ← can be used to return to a previous screen.

Set Up Screen

Selecting the Set Up option will display the device connections screen (Figure 3-17).

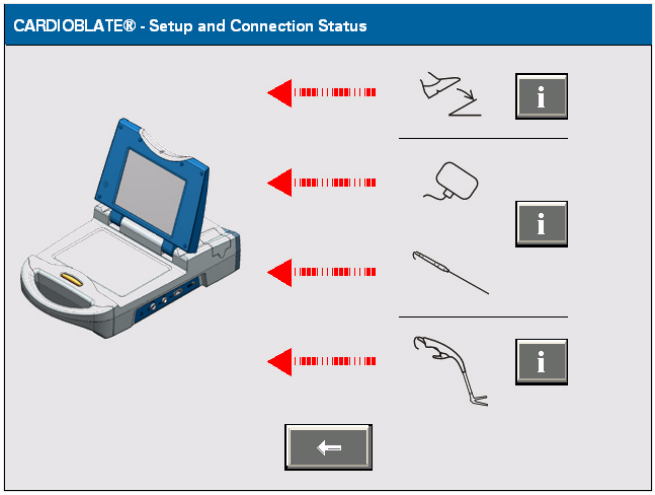


Figure 3-17. Setup and Connections Status screen

- The Setup and Connections Status screen indicates which devices the generator recognizes as being currently attached. Next to each device is an Information button i for selecting the information screen.
- The information screen provides detailed instructions for setting up and attaching the devices to the generator.
- Additional information is provided for the monopolar and bipolar devices by selecting the Setup button displayed on the information screen.

Limits Screen

Selecting the Limits option will bring up the limits selection screen (Figure 3-18).

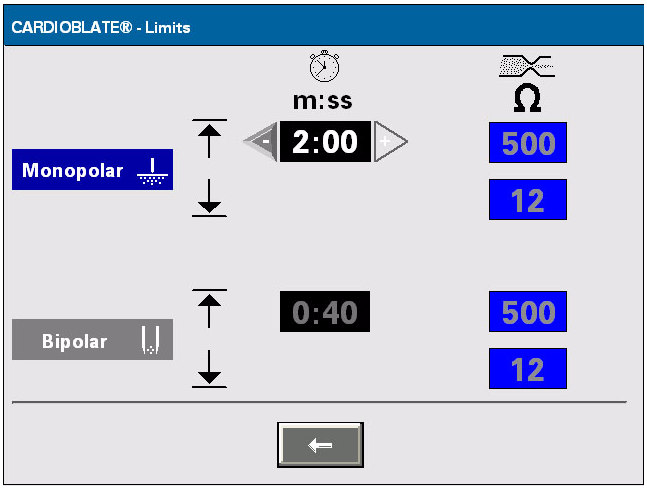


Figure 3-18. Limits screen

The time and impedance limits are listed for the bipolar and monopolar devices. Only the RF Timer Limit for monopolar mode can be adjusted.

1. Adjust the RF Timer Limit in 1-second increments by pressing ▶ to increase or ◀ to decrease the value.
2. Verify the parameters are set properly before depressing the remote control foot switch or pressing the RF button RF to deliver energy.

Note: The RF Timer Limits can be changed at any point during the procedure as long as RF energy is not active.

Note: Maximum and minimum limits cannot be altered.

Advanced Screen

Selecting the Advanced option will bring up the advanced options screen (Figure 3-19).

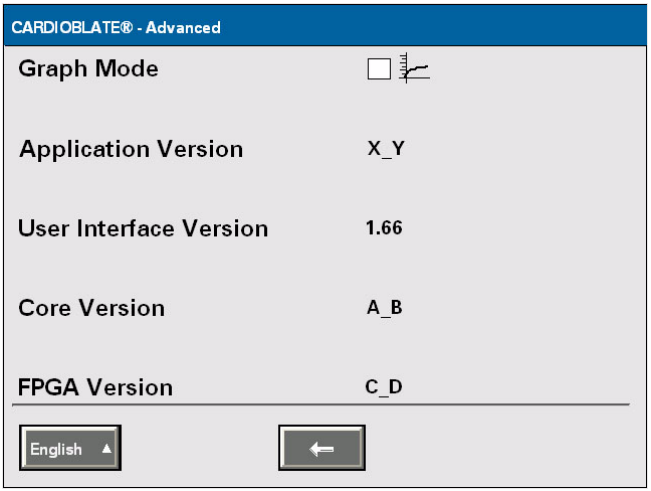


Figure 3-19. Advanced screen

This screen includes the following parameters:

- Graph selection: This allows the user to turn on or off the display of the impedance/power graph on the RF Panel screen. Touch the button to enable the graph. Figure 3-20 shows the RF Panel when graph mode is selected.

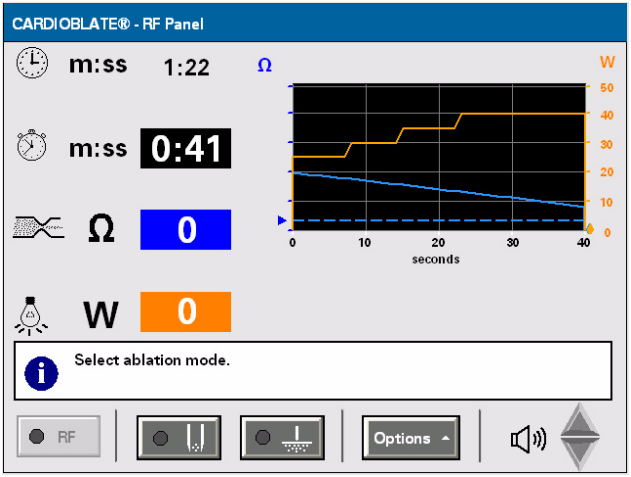


Figure 3-20. RF Panel in graph mode

The Advanced screen also displays the following software information:

- Application Version
- User Interface Version
- Core Version
- FPGA Version

Changing the Language Option

Note: English is the default language for the Cardioblate® Generator.

Press the Language button located in the lower left-side of the Advanced Options screen. Select the desired language. The following languages are available for use:

- English
- German
- Spanish
- French
- Italian
- Greek

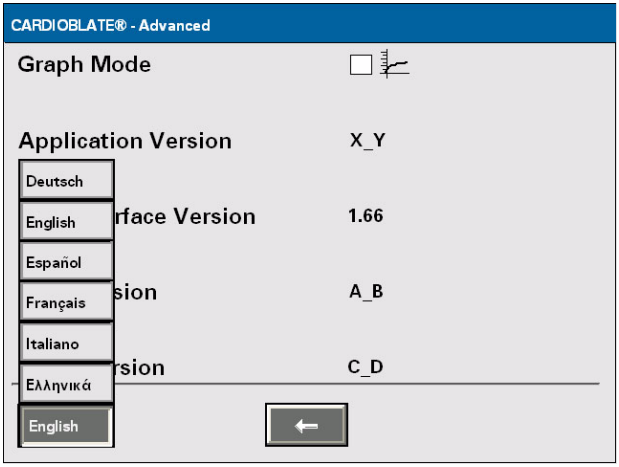


Figure 3-21. Changing Language Option Screen

Optional Connections

Caution: Peripheral equipment connected to the Cardioblate® Generator and any system formed by the generator and the connected peripherals shall be certified according to the respective IEC standards (eg, IEC 950 for data processing equipment and IEC 60601-1 for medical equipment). It is the responsibility of the person who connects the peripheral equipment to comply with the required standards. Consult the Technical Services Department or your local representative if additional information is required.

The following connection is optional:

Electrogram (EGM) Monitoring System

Note: For this option, a Medtronic Model 05328 EGM cable is required.

To connect an EGM monitoring system to the generator using the EGM cable, do the following:

1. Position the metal EGM cable connector so that the red dot is on top.
2. Insert the connector into the EGM connector on the generator side panel until the connector locks into place. Do not force the connection.
3. Connect the opposite end of the cable to the EGM monitor.

Note: To disconnect the EGM cable from the generator, pull back on the textured grip ring to release the lock before removing the connector.

Caution: If noise is noted on the EGM during RF power delivery, try the following to diminish noise:

- Remove surface ECG skin electrodes and the dispersive electrode. Prepare these areas and apply new skin electrodes and the dispersive electrode according to instructions in the manufacturer's product literature.
- Turn off other equipment in the room if possible.

Powering Down the Generator

Turn Off the Generator

1. Turn OFF the generator by pressing the AC power button located on the rear panel.
2. Disconnect all of the devices.
3. Close the display.
4. Discard single-use ablation devices per standard procedure.

Safety Shutdown and Troubleshooting 4

Safety Shutdown Conditions 4-2

Safety Shutdown Messages 4-3

Other Messages 4-6

System Shutdown 4-7

Safety Shutdown Conditions

The generator will perform a safety shutdown to prevent an unsafe operating condition. During a safety shutdown, RF energy delivery will stop and will not be initiated again until the condition that caused the safety shutdown is resolved.

Alert Messages

An alert message occurs when the generator detects a problem. An alert message can appear on the screen either during a lesion, before a lesion, or after a lesion. Alert messages also include the probable cause and the recommended corrective action.

If an alert condition occurs with the RF energy ON, the alert automatically stops the lesion. It turns OFF the RF energy output to both channels. The simultaneous lesion abort and alert message comprises the system's safety shutdown feature.

All system alert messages require some corrective action by the user.

Some alert messages stay on the LCD screen until the user clears the causing condition.

There is also an audible alarm for each message.

The following will occur during a safety shutdown:

- RF energy is terminated.
- The generator beeps three times.
- All controls become inactive until the safety shutdown condition is resolved.
- Blue LEDs turn off.
- An “alert” message displays on the LCD screen and remains on until the cause is corrected.

The following sections present possible causes of and possible solutions for several safety shutdown messages.

If the surgical ablation system does not operate properly after taking the steps listed in the tables or listed in the message itself, contact technical support as listed on the rear panel of the device or your local Medtronic representative.

Safety Shutdown Messages

Table 4-1. Safety shutdown messages

Error message	Possible cause	Possible solution
"Ablation stopped: Device not attached."	The device was disconnected from the generator while an ablation was in process.	1) Reattach device. 2) Restart the ablation.
"Ablation stopped: Maximum ablation time exceeded."	The maximum time limit has been reached.	**In Monopolar Mode:** 1) Check the maximum time and adjust time limit if necessary. 2) Restart the ablation. **In Bipolar Mode:** 1) Halt the ablation after transmurality has been indicated. 2) Restart the ablation.
"Current limit exceeded."	The maximum current limit for the generator has been reached.	1) Turn the generator OFF then ON.
"Device error. Invalid device attached."	A malfunctioning device or a device that does not conform to the specifications of this generator has been detected.	1) Replace the ablation device.
"Device error. Replace device."	The device has been previously used.	1) Replace the ablation device.
"Dispersive electrode not attached."	The dispersive electrode is not attached to the generator.	1) Reattach the dispersive electrode. 2) Restart the ablation.
	The dispersive electrode is faulty.	1) Replace the dispersive electrode. 2) Restart the ablation.

Table 4-1. Safety shutdown messages (continued)

Error message	Possible cause	Possible solution
"Footswitch error. Cannot detect footswitch."	The foot switch connection is faulty.	1) Verify the foot switch connection. 2) Turn the generator OFF then ON.
	The foot switch is faulty.	1) Remove or replace the foot switch.
"Generator overheated. Turn generator OFF and allow to cool."	The internal temperature limit of the generator has been exceeded.	1) Turn the generator OFF. 2) Allow the generator to cool. 3) Ensure that the fan located on the rear panel and the air intake vents on the bottom of the generator are not blocked. 4) Turn the generator ON.
"Internal error. Turn generator OFF then ON."	A problem has been detected with one of the generator's hardware components.	1) Turn the generator OFF then ON.
"Internal software error. Turn generator OFF then ON."	An invalid parameter was specified by the software.	1) Turn the generator OFF then ON.
"Limit exceeded. High dispersive electrode impedance."	The dispersive electrode connection is faulty.	1) Reattach the dispersive electrode. 2) Restart the ablation.
	The dispersive electrode is faulty.	1) Replace the dispersive electrode. 2) Restart the ablation.
"Limit exceeded: High impedance. Restart ablation to continue."	Lifting of electrode from tissue while electrode is active.	**In Monopolar Mode:** 1) Place the electrode on target tissue. 2) Reapply power.
	Restricted irrigation flow	1) Check irrigation set-up to ensure good flow to electrodes (pressure bag inflated between 150-300 mm Hg, 1000 mL bag of normal saline, all clamps on line open).

Table 4-1. Safety shutdown messages (continued)

Error message	Possible cause	Possible solution
		In Monopolar Mode:
	The dispersive electrode/ablation device connection is faulty.	1) Verify the connection of the dispersive electrode to the patient, the dispersive electrode cable to the electrode and to the generator. 2) Verify the connection of the ablation device to the generator. 3) Restart ablation.
		In Bipolar Mode:
	Coagulum formed on the ablation electrode of the ablation device.	1) Replace ablation device. 2) Restart ablation.
	The ablation device is faulty.	1) Replace the ablation device. 2) Restart ablation.
	Restricted irrigation flow	1) Check irrigation set-up to ensure good flow to electrodes (pressure bag inflated between 150-300 mm Hg, 1000 mL bag of normal saline, all clamps on line open).
"Limit exceeded: Low impedance. Restart ablation to continue."		**In Monopolar Mode:**
	The dispersive electrode is improperly placed.	1) Move the dispersive electrode farther from the heart. 2) Reapply power.
	The ablation device is faulty.	1) Replace the ablation device. 2) Reapply power.
		In Bipolar Mode:
	The device electrodes are in direct contact.	1) Open the jaws of the bipolar electrodes. 2) Reposition on the tissue so that the electrodes are not in direct contact. 3) Reapply power.
	The ablation device is faulty.	1) Replace the ablation device. 2) Reapply power.

Table 4-1. Safety shutdown messages (continued)

Error message	Possible cause	Possible solution
"Power measurement error: P<>VI. Restart ablation to continue."	This occurs when the internal power calculation falls outside of the acceptable range during ablation.	1) Restart ablation to continue.
"Power measurement error. Restart ablation to continue."	This occurs when the wattage readings fall outside the acceptable range during ablation.	1) Restart the ablation to continue.
"XXXX system error. Turn generator OFF then ON."	A problem with the generator has been detected.	1) Turn the generator OFF then ON.
"Voltage limit exceeded. Restart ablation to continue."	The maximum voltage limit for the generator has been reached.	1) Turn the generator OFF then ON.

Other Messages

Table 4-2. Other messages

Message	Explanation
"Ablating"	RF energy is being delivered.
"Ablation stopped. Press RF button or footswitch to start ablation."	RF energy has terminated and needs to be restarted to continue ablating.
"No devices are attached."	The generator is ready for the device to be attached.
"Press RF button or footswitch to start ablation."	RF energy is not active and needs to be started to ablate.

Table 4-2. Other messages

Message	Explanation
"Select ablation mode."	Ablation mode, bipolar or monopolar, must be selected to activate a device. RF energy will only flow to one device at a time.
"Transmurality reached. Power is ON"	The generator algorithm notes that a transmural lesion has been obtained. A solid tone is emitted from the generator. Energy delivery will continue until the user releases the foot switch, presses the power button on the generator, releases the jaws and eliminates contact with the tissue, or the maximum time limit is reached.

System Shutdown

When a complete system shutdown occurs, a solid blue screen will appear on the display panel. If this occurs, please note the error message on the screen and contact technical support as listed on the rear panel or your local Medtronic representative.

Chapter 4
System Shutdown

Device Maintenance and Service 5

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Cleaning the Generator 5-2

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End of Life Disposition 5-5

Replacing the Generator Fuse

The Cardioblate® Generator has two 250 V 3.15 Amp. slow-blow fuses that can be replaced in the field.

Replacing the Fuse

Refer to Figure 5-1 along with the following instructions.

1. Pull out the door of the fuse housing.
2. Replace the fuses.
3. Push in the door of the fuse housing.

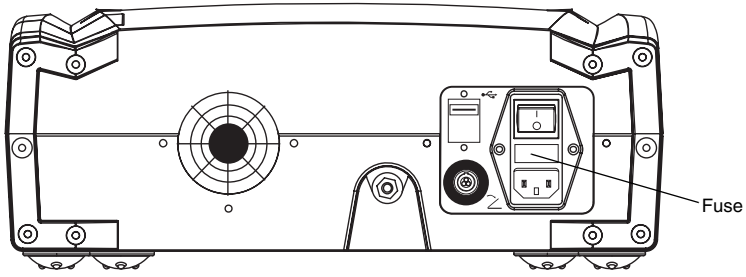

Figure 5-1. Replacing fuse

Cleaning the Generator

Caution: Do not clean the components of the generator with aggressive solvents or the equipment may be damaged.

Caution: Do not immerse the components for cleaning.

Cleaning the Components of the Cardioblate® Surgical Ablation System

1. Clean the generator and its components by wiping them with a damp cloth. If necessary, use a mild detergent to remove all visible blood and body fluid contaminants.
2. Dry all of the components completely.

Periodic Technical and Safety Inspection

Technical and safety inspections of the generator and its accessories must be performed at least once every 12 months by persons, who, based on their training, knowledge, and practical experience, are capable of adequately performing such inspections and who do not require instructions with regard to the technical and safety inspection.

Warning: If technical and safety inspection reveals a defect that could harm the patient, users, or third parties, the device should not be used until it has been properly repaired. The operator must immediately notify the appropriate authorities and Medtronic of these defects.

Visual Inspection

The following must be visually inspected:

- The technical manual is available and complete.
- Labels, cautions, or warnings are placed correctly and in all required locations.
- The device, accessories, and all wiring show no signs of physical damage.

Operating Test

The following must be tested for functionality:

- Foot switch
- Touch screen: buttons and displays
- Audio output

Electrical Safety Test: IEC 60601-1

Follow test instructions in the appropriate area of the standard.

- Protective earth resistance: 0.1 ohm
- Earth leakage current: 0.5 mA (500 μA)
- Enclosure leakage current: 0.1 mA (100 μA)
- Patient leakage current: 0.01 mA (10 μA)
- Patient auxiliary current (dc): 0.01 mA (10 μA)
- Patient auxiliary current (ac): 0.01 mA (10 μA)

Caution: USE EXTREME CAUTION WHEN WORKING AROUND TEST LEADS AND LOADS WHILE RF ENERGY IS BEING APPLIED. DO NOT TOUCH ANY EXPOSED LEADS. USE INSULATED LEADS IF POSSIBLE. RISK OF SHOCK OR TISSUE ABLATION EXISTS WITH THESE NONCLINICAL SET UPS.

Functional Test

In order to perform critical functional tests of the Medtronic® Cardioblate® Generator Model 68000, specific software and hardware are required which is available for purchase from your local Medtronic representative. Specific instructions on how to perform these tests are included as part of the Medtronic® Cardioblate® Diagnostic Kit (Model 60889).

Service

Medtronic employs highly trained representatives and engineers located throughout the world to serve you and, upon request, to provide training to qualified hospital personnel in the use of Medtronic products. Medtronic also maintains a professional staff to provide technical consultation to product users. For medical consultation, Medtronic can often refer product users to outside medical consultants with appropriate expertise. For more information, contact your local Medtronic representative, or call or write Medtronic at the appropriate address or telephone number listed on the back cover.

The Cardioblate® Surgical Ablation System Model 68000 has been carefully engineered, manufactured and quality tested to provide long, trouble-free service. Should service or repair be necessary, contact your local Medtronic representative at the appropriate address or telephone number listed on the back cover.

Note: Ship the Cardioblate® Surgical Ablation System Model 68000 back to Medtronic in its original shipping container. If the original shipping container is not available, contact your Medtronic representative.

A serial number identifying each individual device is printed on the back of the device. This serial number should be referenced in any correspondence regarding this device.

Contact your local Medtronic representative for replacement parts, such as cables, footswitches.

At the end of its useful life, dispose of the Cardioblate® Surgical Ablation System Model 68000 in accordance with local environmental requirements.

End of Life Disposition

Do not dispose of this product in the unsorted municipal waste stream. Follow local regulations for proper disposal. Please refer to Medtronic web site http://recycling.medtronic.com for proper disposal guidance to ensure compliance with the European Union's Waste Electrical and Electronic Equipment (WEEE) Directive.

Chapter 5
End of Life Disposition

Warranty 6

Medtronic Warranty Information 6-2

Medtronic Warranty Information

Limited Warranty for the Model 68000 Generator

A. This LIMITED WARRANTY provides the following assurance to the purchaser of the Medtronic® Cardioblate® Model 68000 generator, hereafter referred to as the "Equipment," that should the Equipment fail to function within normal tolerances due to a defect in materials or workmanship within a period of one year, commencing with the delivery of the Equipment to the purchaser, Medtronic will at its option: (a) repair or replace any defective part or parts of the Equipment; (b) issue to the purchaser a credit equal to the original Equipment purchase price (but not to exceed the value of the replacement Equipment), against the purchase of replacement Equipment, or (c) provide functionally comparable replacement Equipment at no charge.

B. To qualify for this repair, replacement or credit, the following conditions must be met:

   (1) The Equipment must be returned to Medtronic within sixty (60) days after discovery of the defect (Medtronic may, at its option, repair the Equipment on site).

   (2) The Equipment must not have been repaired or altered by someone other than Medtronic in any way that, in the judgment of Medtronic, affects its stability and reliability.

   (3) The Equipment must not have been subjected to misuse, abuse or accident.

C. This LIMITED WARRANTY is limited to its express term. In particular, Medtronic is not responsible for any incidental or consequential damages based on any use, defect or failure of the Equipment, whether the claim is based on warranty, contract, tort or otherwise.

D. The exclusions and limitations set out above are not intended to, and should not be construed so as to, contravene mandatory provisions of applicable law. If any part or term of this LIMITED WARRANTY is held by any court of competent jurisdiction to be illegal, unenforceable or in conflict with applicable law, the validity of the remaining portion of the LIMITED WARRANTY shall not be affected, and all rights and obligations shall be construed and enforced as if this LIMITED WARRANTY did not contain the particular part or term held to be invalid.

Disclaimer of Warranty for the Accessories

Although the Medtronic® Model 60883 remote control foot switch, Models 4807, 4808, and 4809 power cords, Model 05328 EGM cable, hereafter referred to as “Product,” have been carefully designed, manufactured and tested prior to sale, the Product may fail to perform its intended function satisfactorily for a variety of reasons. The warnings contained in the Product labeling provide more detailed information and are considered an integral part of the DISCLAIMER OF WARRANTY. Medtronic, therefore disclaims all warranties, both express and implied, with respect to the Product. Medtronic shall not be liable for any incidental or consequential damages caused by any use, defect, or failure of the Product, whether the claim is based on warranty, contract, tort or otherwise.

The exclusions and limitations set out above are not intended to, and should not be construed so as to contravene mandatory provisions of applicable law. If any part or term of the DISCLAIMER OF WARRANTY is held by any court of competent jurisdiction to be illegal, unenforceable or in conflict with applicable law, the validity of the remaining portion of the DISCLAIMER OF WARRANTY shall not be affected, and all rights and obligations shall be construed and enforced as if this DISCLAIMER OF WARRANTY did not contain the particular part or term held to be invalid.

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Medtronic Warranty Information

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Appendix A

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M928339A001 Rev. B